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DISCLAIMER

This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Bucharest, Romania for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Section I. Food Laws

Several different Government agencies and ministries in Romania have responsibilities related to agri-food production and food importation. The most relevant legal provisions governing agricultural production, food processing and agri-food products, applicable to both domestic and imported products, are outlined below:

- Government Ordinance 42/2004 regarding the organization of veterinary activity with subsequent amendments;
- Government Decision 106/2002 concerning food labeling with subsequent amendments;
- Government Ordinance 34/2000 concerning organic food amended by MARD Order 219/2007 providing instructions for producers, processors, and importers of organic products;
- Emergency Ordinance 43/2007 transposing [Directive 2001/18](#) regarding the deliberate release into the environment of genetically-modified organisms;
- Emergency Ordinance 44/2007 transposing [Directive 90/219](#) referring to contained use of genetically-modified micro-organisms.
- Veterinary Authority Order 213/2008 concerning the national surveillance and control program for food safety approved for 2008.

The main bodies with responsibilities covering agricultural production, food processing as well as food importation are the following:

The Ministry of Agriculture and Rural Development (MARD)

The Ministry of Agriculture and Rural Development is the specialized body of the central public administration with governmental jurisdiction. It applies the Government's strategy in the field of agriculture, food processing, as well as rural development and forests management.

The Ministry of Environment and Sustainable Development (MESD)

Ministry of Environment and Sustainable Development is the main body conducting environmental risk assessment (including for genetically modified organisms) and monitoring activities that might have adverse effects on human health and the environment.

The National Sanitary Veterinary and Food Safety Authority (NSVFSA)

This is the main body in charge with sanitary-veterinary and food-safety activities. The Authority performs activities related to animal health and foodstuffs of animal and non-animal origin, as well as food safety.

The Ministry of Public Health (MPH)

The Ministry of Public Health is responsible for overseeing the production and registration of drugs, food additives, and medical equipment. It is also responsible for the public health as it relates to food and contaminants.

The National Authority for Consumers Protection (NACP)

The National Authority for Consumers Protection is the Government agency established with the aim of protecting the consumers' rights and interests. NACP is actively involved in

proposing, endorsing and promoting legislation related to consumer protection, including food products.

Section II. Labeling Requirements

A. General Requirements

The methodology and requirements for food labeling are established by the GOR Decision 106/2002 - further detailed in its accompanying Methodological Norm 7/2002. The GOR Decision 106/2002 was amended by GOR Decision 1529/2007, transposing the provisions of [Council Directive 2006/107/EC](#) of 20 November 2006 adapting Directive 89/108/EEC related to quick-frozen foodstuffs for human consumption, and [Directive 2000/13/EC](#) of the European Parliament and of the Council related to the labeling, presentation and advertising of foodstuffs. For further details on the EU labeling regime, please see the specific section in the [EU 27 FAIRS Report E48078](#).

Biotechnology Labeling

All provisions regarding biotechnology labeling remain unchanged ([GAIN Report RO7004](#)).

In September 2007, several members of the Romanian Parliament proposed a draft law for labeling products containing genetically modified ingredients. According to the proposal, the label should have contained the warning "Attention this product contains genetically modified organisms" written in black color inside a yellow spot. This warning should have covered 30% of the total surface of the product. Following the legal provisions, the Romanian Government (GOR) analyzed this proposal and strongly rejected it. Further both Chambers of Romanian Parliament, Senate and Chamber of Deputies, declined the initiative on grounds related to the existing biotech provisions.

Organic Labeling

Imported products should be labeled as "organic" if they were produced by organic methods confirmed by the certificate of compliance. According to GOR Ordinance 34/2000, the product label must contain: the name and the address of the producer/processor, the name of the product and the ecological production method, the name and the mark of the inspecting and certifying institution, the storage conditions, the minimum term of validity, the interdiction to store the ecological products along with ordinary products.

Order 317/2006 issued by Min. of Agriculture stating that for organic food labeling and advertisement the emblem "ae" (**a**gricultura **e**cologica = organic agriculture) should be used is still valid. The emblem belongs to the Ministry of Agriculture and can be applied on the product, on the label or on the package. The regulation refers to both domestic and foreign products. More details on organic food can be found in [GAIN Report RO8010](#).

B. Requirements Specific to Nutritional Labeling

Please see the specific section in the [EU 27 FAIRS Report E48078](#).

Section III. Packaging and Container Requirements

Please see the specific section in the [EU 27 FAIRS Report E48078](#).

Section IV. Food Additive Regulations

Order 438/295/2002 defining and listing additives permitted for use in foodstuffs was modified in 2008 through Order 87 issued by Ministry of Health transposing the provisions of [Directive 2006/128/CE](#) laying down specific criteria of purity concerning sweeteners for use in foodstuffs and [Directive 2006/129/CE](#) laying down specific purity criteria on food additives other than colours and sweeteners. For further details on the EU food additive regulations, please see the specific section in the [EU 27 FAIRS Report E48078](#).

Section V. Pesticide and Other Contaminants

Order 299/2006 issued by the National Sanitary Veterinary and Food Safety Authority lays down the provisions for testing the presence of contaminants in non-animal origin products, pesticides residues, including control and surveillance on genetically modified food and feed.

Pesticides and substances residues

Order 299/2006 sets the frequency of testing for pesticide residues in non-animal origin products. The laboratories included in the National Institute for Veterinary Public Health are responsible for conducting tests for determining the presence and level of these pesticides in foodstuffs. The maximum levels of pesticides residues in and on fruits, vegetables, grains and other products of non-animal origin are provided by Order 12/2006, issued by Veterinary Authority jointly with Ministry of Agriculture and Ministry of Public Health. However, this order was amended to reflect the changes in legislation at EU level, namely [Council Directive 86/362/EEC](#) establishing maximum residues levels (MRL) for pesticides in cereals and cereal products, [Council Directive 90/642/EEC](#) establishing MRLs for pesticides in products of plant origin, including fruits and vegetables and [Commission Directive 2007/7/CE](#). In 2008, Order 12/2006 was again modified by Order 12/2008, transposing the provisions of [Commission Directive 2007/55/CE](#), [Commission Directive 2007/56/CE](#), [Commission Directive 2007/57/CE](#), [Commission Directive 2007/62/CE](#) and [Commission Directive 2007/73/CE](#).

Veterinary Order 207/2007 transposes into national legislation [Council Directive 86/363/CEE](#) on setting up the maximum levels for pesticide residues in and on foodstuffs of animal origin and amendments for Annex II of the [Commission Directive 2007/55/CE](#), [Commission Directive 2007/56/CE](#), [Commission Directive 2007/57/CE](#). Furthermore, Veterinary Authority issued in 2008 Order 61 completing the pesticide residues legislation and transposing [Commission Directive 2008/17/EC](#).

The provisions of Veterinary Order 95/2007 regarding measures for surveillance and control of certain substances and their residues in live animals and their products, as well as residues of veterinary medicines in products of animal origin remain valid.

Contaminants

Veterinary Order 299/2006 sets the frequency of testing for contaminants, such as aflatoxin, ochratoxin A, cadmium, lead, 3-MCPD, nitrates etc. The laboratories included in the National Institute for Veterinary Public Health are responsible for conducting tests for determining the presence and level of these contaminants in foodstuffs. The maximum levels are provided in the annex of [Regulation 1881/2006](#).

Veterinary Order 213/2007 establishes for 2008 the program for surveillance and control on food safety. The order annexes contain examination programs and sample collection procedures from non-animal products specifically for contaminants, pesticides residues, prohibited food additives, radioactive contamination and genetically modified organisms.

Section VI. Other Regulations and Requirements

Phytosanitary regulations

Phytosanitary regulations provided in the country FAIRS report [GAIN Report RO7004](#) remain valid. Specific marketing and technical rules were approved in 2005 by the Ministry of Agriculture for cereals seeds production (Order 1262/2005, amended through Order 149/2007), fodder plants (Order 1263/2005 amended through Order 148/2007), vegetables propagating and planting material, other than seeds (Order 1269/2005 amended through Order 432/2007), oil and fiber plants seeds (Order 1269/2005 amended through Order 432/2007), beet seeds (Order 1265/2005 amended through Order 147/2007), oilseeds (Order 1264/2005 amended through Order 150/2007), vegetables (Order 1366/2005 amended through Order 433/2007). All these regulations define types of seeds (basic seeds, certified seeds, commercial seeds etc.) for each of the plant varieties. For more details on the EU regime on plants, please visit the website <http://useu.usmission.gov/agri/>.

Order 61/2008 issued by Ministry of Agriculture establishes the procedures of phytosanitary official control in case of import from third countries or intra EU movement of plants, vegetal and related products. Third countries exporters should comply with the following requirements:

- notify the Phytosanitary Quarantine Inspectorate within the Custom Point through which the goods will pass the border, with 24 hours in advance about the transport, in order to facilitate the customs phytosanitary control;
- pay the phytosanitary fees, as per GOR Decision 563/2007 Annex VIII, with subsequent amendments;
- inform the Phytosanitary State Unit within 24 hours when the transport entered European Union through one of the designated entry borders on any member state.

Veterinary regulations

Romania applies the EU regulations in respect to animal products imports from third countries. Detailed information on veterinary requirements for imports of animal origin products, including a list of U.S. establishments approved for EU exports, can be viewed by accessing the website <http://useu.usmission.gov/agri/>.

At the end of 2007, Romania harmonized its import requirements with the EU legislation, removing the supplementary tests performed on frozen semen of bovine species upon importation. In the European Union, the import regime for bovine frozen semen originating from third countries is provided by the [Council Directive 88/407/EEC](#) laying down animal health requirements governing trade and imports into the Community of semen of domestic animals of bovine species, as amended by [Directive 2003/43/EC](#). These directives are transposed into national legislation through of Veterinary Order 45/2008.

The Veterinary Order 38/2007 transposes the [Commission Decision 2006/168](#) regarding the requirements for bovine embryos import from third countries. The Order includes the Health Certificate required by the Veterinary Authority.

In May 2008, Romanian Government approved Decision 515/2008 regarding the new strategic plan for Classical Swine Fever eradication. This disease is still endemic in Romania and it had already triggered an EU ban on all Romanian pig and pork exports starting with 2003. The new plan includes vaccination with “live attenuated” vaccine of all backyard pigs and wild boar using baits, while commercial pig herds will just be monitored for CSF. The new strategic program is setting up bio-security rules and compensation guidance based on provisions of GOR Ordinance 42/2004 and GOR Decision 1415/2004.

The animal health requirements for aquaculture animals and associated products and for prevention and control of certain diseases in aquatic animals are regulated by Order 60/2008 issued by the Veterinary Authority, amending Order 170/2007, and transposing [Commission Directive 2008/53/CE](#) (which amends [Council Directive 2006/88/CE](#)).

Section VII. Other Specific Standards

Novel foods

Please see the specific section in [EU 27 FAIRS Report E48078](#).

Dietetic or special use food

Special nutritional destination food is regulated by provisions of Order 883/2007 issued by the Ministry of Agriculture and Rural Development. The Order is transposing [Commission Directive 2006/82/EC](#) adapting Directive 91/321/EEC on infant formulae and follow-on formulae and [Directive 1999/21/EC](#) on dietary foods for special medical purposes. For more details on the EU regime on dietetic and special use food, please read [EU 27 FAIRS Report E48078](#).

Food Supplements

Order 1228/2005 regulating food supplements was amended by Order 972/2007 approved by Ministry of Agriculture and Ministry of Public Health. According to this regulation, food supplements can be displayed on the market in any of the forms of tablets covered or uncovered, capsules, jellies, pastes, candies or bars, juices, liquids, powders, or other liquid forms, ampoules of liquids, drop dispensing bottles, which contain nutritional substances for human diet. The amendment brought in 2007 refers to issuing the national proposal list of nutritional and healthy notes associated to food products intended for human consumption.

Organic Food

The provisions of Order 219/2007 issued by Ministry of Agriculture providing instructions for producers, processors, and importers of organic products remains valid. According to this Order, published in addition to Emergency Ordinance 34/2000 on organic products, all operators in this field have to register with the Ministry of Agriculture, through its specialized department.

The commercial operators have to fill-out certain forms and submit them to Min. of Agriculture before June 1 every year. No inspection and certification will be granted to un-registered operators. Before certification, farms must undergo a conversion period during which organic principles are implemented to reduce non-approved input residues in the fields. Due to minimal use of fertilizers and pesticides on Romanian farmland over the past fifteen years, reduced transition periods are frequently offered to potential producers. While farmers in EU countries can face transition periods of five or six years, a typical conversion period in Romania is as low as one or two years.

Products derived from Biotechnology

The national legislation concerning the biotech products has been in a limited extent subject to changes during 2007-2008. One significant development worth to note is Order 98/2008 issued by Ministry of Environment and Sustainable Development, which draws the organization and functions of the BioSafety Commission. The Commission is composed of 12

full members and 4 supplementary members named by the head of Central Public Authority of Environment Protection. The Biosafety Commission has a consultative scientific role on decisions made by the competent authority. The Commission has to analyze scientific data and make assessments of the environmental risks in case of biotech products

Section VIII. Copyright and/or Trademark Laws

Please see the specific section in [GAIN Report RO7004](#).

Section IX. Import Procedures

The animal and products list which must undergo examination at the Romanian entry borders is provided by Order 155/2007, which is transposing [Commission Decision 2007/275/EC](#). The border points where import, export and transit of vegetal and related products are permitted are stipulated in Order 340 issued by Ministry of Agriculture.

Non-animal origin products

The import and export conditions for products of non-animal origin are regulated by the Veterinary Order 145/2007. As per this order, the importer has to provide the border entry point through the goods will pass detailed information about the shipment with 24 hours before arrival. Each shipment has to be accompanied by this notification in original. Placing on the market of the imported goods will be allowed upon presenting the authorities with the test results for contaminants, pesticide residues etc.

Specific import requirements for products coming from third countries, reflecting the aflatoxin risk contamination, are established by Order 215/2008 issued by Ministry of Agriculture, transposing [Commission Decision 2006/504/CE](#). Article 8 of the above mentioned order contains the supplementary conditions for imports coming from United States of America. The aflatoxin analysis must be conducted by a USDA certified laboratory or a laboratory which is under certification process in conformity with EN ISO/IEC 17025. The Health Certificate which should accompany the transport is included in the annex of the referred order.

Import of plant protection products from third countries is permitted based on an authorization certificate, as per Law 22/2008. The authorization certificate is issued by Phyto-Sanitary Local Offices, under the supervision of Ministry of Agriculture, on the importer's name and attests the authorization to import these products into Romania. The buyer/importer is required to submit a dossier with all the required documentation in order to obtain the authorization, to announce the Phyto-Sanitary Office on any modification that may occur after submitting the documents and to use the authorization certificate just for its issued purpose.

Animal origin products

The conditions and the sanitary veterinary procedure for import, export, and transit of live animals, products and by-products of animal origin are identical to the ones at EU level.

Import of poultry and incubation eggs from third countries and intra-community trade are currently regulated by Order 210/2007 issued by the Veterinary Authority. The order is transposing the [Council Directive 90/539/CEE](#), regarding the animal health conditions governing intra-Community trade and imports from third countries of poultry and hatching eggs, amended by [Commission Decision 2007/594/CE](#). For further details on health certificates and import requirements you can read [EU 27 FAIRS Report E48078](#).

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E-mail: comunicare@madr.ro
Web site: <http://www.madr.ro>

The Ministry of Public Health

1-3, Cristian Popisteanu Str., sector 1, 010024
Bucharest, Romania
Phone: 40 21 3072500 or 40 21 3072600
Fax: 40 21 3141526
Web site: <http://www.ms.ro>

The National Sanitary-Veterinary and for Food Safety Authority

1B Negustori Street, sector 2
Bucharest, Romania
Phone: 40 21 3157875
Fax: 40 21 3124967
Website: <http://www.ansv.ro>

The Ministry of Environment and Sustainable Development

12 Libertatii Blvd., Sector 5
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The National Authority for Consumers Protection

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The National Customs Authority

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Institute of Food Bioresources

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